UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/685,912	10/15/2003	William Fiehler	47563.0011	6302

57600 7590 11/12/2008

HOLLAND & HART LLP
60 E. South Temple, Suite 2000
P.O. Box 11583
Salt Lake City, UT 84110

EXAMINER	
RYCKMAN, MELISSA K	

ART UNIT	PAPER NUMBER
3773	

MAIL DATE	DELIVERY MODE
11/12/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/685,912	FIEHLER ET AL.	
	Examiner	Art Unit	
	MELISSA RYCKMAN	3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 August 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to claims filed 8/14/08.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-SSS are rejected under 35 U.S.C. 102(b) as being anticipated by Akerfeldt et al. (U.S. Patent No. 6,860,895).

Regarding Claim 1, Akerfeldt teaches a tissue puncture system comprising:

- A tissue puncture closure device for partial insertion into and sealing of an internal tissue wall puncture (Fig. 8), the device comprising:
    - a filament (6) extending from a first end of the closure device to a second end of the closure device
    - an anchor (2) for insertion through the tissue wall puncture, the anchor being attached to the filament at the second end of the closure device (Fig. 5)
    - a sealing plug (3) slidingly attached to the filament and positioned adjacent to the anchor (fig. 2)
    - a tamping tube (33) disposed adjacent (Fig. 4) to the sealing plug
    - a handle (36) located at the first end of the closure device

- and an automatic driving mechanism (44) located within the handle that tamps the sealing plug (3) utilizing force generating by withdrawal of the closure device from the internal tissue wall puncture (Fig. 5) to move the tamping tube toward the sealing plug (Fig. 5).
- The automatic driving mechanism (44) comprises a transducer (40) for effecting movement of the tamping tube toward the sealing plug upon withdrawal of the closure device from the tissue wall puncture (Fig. 5)
- The transducer comprises
  - A spool (40) with a portion of the filament wound thereon (Fig. 5)
  - A gear (38) engaged with the spool (Fig. 4)
  - A tamping tube driver indirectly driven by the gear (Figs. 3-5)
- The tamping tube driver comprises a flexible rack slidingly disposed about the filament (Figs. 3-5)
- The filament extends at least partially back from the anchor toward the proximal end and re-engages the sealing plug (Figs. 3-5)
- The means for automatically driving further comprises means for increasing linear velocity of a sealing plug driver relative to the linear velocity of withdrawal of the closure device (Figs. 3-5, this is inherent)

- Transducing a motive force generated by retraction (33 surrounded by 22) of a proximal end of the filament from the tissue closure device to a linear tamping force upon the sealing plug
- A torque limiting clutch (42) disposed between the spool (40) and the first gear (38)

- A method of sealing a tissue puncture in an internal tissue wall accessible through a percutaneous incision (Figs. 3-5);
  - Withdrawing a closure device from the percutaneous incision (3 is withdrawn, Fig. 5)
  - Automatically tranducing a motive force (F1) generated by withdrawal of the closure device is a first direction to move a tamping member to provide a tamping force is a second direction (23 causes a tamping force on 3) to a sealing plug, wherein the force is generated by an automatic driving mechanism located within a handle of the closure device (Fig. 5)
  - The transferring further comprises automatically unwinding the filament from a spool by deploying an anchor attached to the filament inside the tissue puncture, and withdrawing the closure device form the tissue puncture (Figs. 3-5)
  - The automatic unwinding of the filament from the spool comprises rotating the spool, and wherein spool rotation comprises the motive force (Figs. 3-5)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 7,10-13,19-26,28,30,33,36,38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Akerfeldt et al. (U.S. Patent No. 6,860,895).

Akerfeldt teaches a transducer (32) however does not teach an electronic switch or an optical sensor, however it is well known in the art to use an electronic switch as using electric power is well known in the art. It is well known in the art to use an optical sensor, as optical sensors provide great accuracy and are well known and successful in the art.

Akerfeldt teaches the claimed invention in the embodiment as shown in figures 3-5, however does not show a mechanical gear train in this embodiment. However, in Fig. 8 of Akerfeldt there is a mechanical gear train including a gear rack, it would have been obvious to one of ordinary skill in the art to use a mechanical gear train as this is a well known and effective way of causing an object to move.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims

are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-39 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the claims of copending Application Nos. 11/130895, 11/130688, 11/103730 and 11/103257. Although the conflicting claims are not identical, they are not patentably distinct from each other because they relate to the same inventive concept, that being a tissue puncture closure device comprising a filament, an anchor, a sealing plug and an automatic driving mechanism for automatic tamping, including a transducer, a spool, a gear, a torque limiting clutch etc.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Regarding the provisional double patenting rejections

The previous provisional patenting rejection with respect to applications 11/130895, 11/130688, 11/103730, 11/103257 are still outstanding. Examiner acknowledges applicants remarks with respect to these applications, however examiner points out that this is a provisional obvious-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA RYCKMAN whose telephone number is (571)272-9969. The examiner can normally be reached on Monday thru Friday 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571)-272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MKR
/Melissa Ryckman/
Examiner, Art Unit 3773

/(Jackie) Tan-Uyen T. Ho/
Supervisory Patent Examiner, Art Unit 3773